**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION | CIVIL ACTION NO. 05-340 |
| THIS DOCUMENT RELATES TO *CVS and Rite Aid* (05-605) | Hon. Kent Jordan, U.S.D.J. |

## AMENDED COMPLAINT

Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation, and Rite Aid Hdqtrs. Corp. (collectively "Plaintiffs") sue Defendants Abbott Laboratories, Fournier Industrie et Santé, and Laboratories Fournier S.A., and for their Amended Complaint allege as follows:

### Nature of the Action

1. This is a civil antitrust action seeking treble damages and other relief arising out of Defendants' unlawful monopolization of the market for fenofibrate, a drug used to lower cholesterol and triglycerides, which is manufactured and sold by Defendants under the brand name TriCor. As described in more detail below, Defendants have unlawfully delayed and impeded generic competition by numerous means, including modifying the TriCor product for the purpose of preventing pharmacists from substituting a generic product for branded TriCor. Defendants' exclusionary conduct had the purpose and effect of maintaining Defendants' monopoly in the fenofibrate market. Defendants' unlawful conduct has deprived Plaintiffs and other purchasers of the benefits of generic competition from mid-2002 through the present.

**Parties**

2. Plaintiff CVS Corporation is a corporation organized and existing under the laws of the State of New York, with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. CVS purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 4,100 drugstores operated by its affiliates. During the relevant period, CVS purchased TriCor directly from Defendants as well as from wholesalers, McKesson Corporation, Cardinal Health, Inc., Bindley-Western, Inc. and National Pharma-Pak (the "CVS Wholesalers"). CVS brings this action in its own right and as the assignee of the CVS wholesalers, which purchased TriCor directly from Defendants during the relevant period for resale to CVS. The CVS Wholesalers each purchase TriCor directly from Defendants and have assigned to CVS their antitrust claims with respect to TriCor that was subsequently resold to CVS.

3. Plaintiff Rite Aid Corporation and Rite Aid Hdqtrs. Corp., with a principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011, are corporations organized and existing under the laws of the State of Delaware (collectively "Rite Aid"). Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 3,500 drugstores operated by its affiliates. During the relevant period of time, Rite Aid has purchased TriCor from wholesaler McKesson Corporation. McKesson purchases TriCor directly from Defendants and has assigned to Rite Aid its antitrust claims with respect to TriCor that was subsequently resold to Rite Aid. Rite Aid brings this action in its own right and as the assignee of McKesson.

4. Defendant Abbott Laboratories ("Abbott") is an Illinois corporation having its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures

and sells brand-name pharmaceutical products and other products in the United States and elsewhere.

5. Defendants Fournier Industrie et Santé and Laboratories Fournier, S.A. (collectively "Fournier") are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France.

6. Defendants Abbott and Fournier acted in concert in devising and carrying out the anticompetitive scheme described below. Each Defendant authorized and knowingly participated in each of the unlawful acts alleged below, and each Defendant received the benefits of those unlawful acts.

## Jurisdiction and Venue

7. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15(a) and 26. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1337(a).

8. Venue is proper in this Court pursuant to section 12 of the Clayton Act, 15 U.S.C. §22, because each Defendant is an inhabitant of this District or is found or transacts business here.

## Trade and Commerce

9. The pharmaceutical products at issue in this case are sold in interstate commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

## Characteristics of the Pharmaceutical Marketplace

10. The market for the sale of pharmaceutical products in the United States contains a significant imperfection that can be exploited by manufacturers in order to obtain or

extend a monopoly in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the price of their products.

11. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including fenofibrate, to patients without a prescription written by the patient's physician. The prohibition on dispensing certain products without a prescription introduces a "disconnect" in the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses which product the patient will buy.

12. Many pharmaceutical manufacturers, including defendant Abbott, exploit this defect in the pharmaceutical marketplace. The so-called "brand manufacturers" (*i.e.*, the manufacturers of branded, as opposed to generic, pharmaceuticals) employ large forces of sales representatives, known as "detailers," who visit physicians' offices in an effort to persuade physicians to prescribe the manufacturer's products. Importantly, these detailers do not advise the physicians of the cost of the branded products. Studies show that physicians typically are not aware of the relative costs of branded pharmaceutical products and that, even when physicians are aware of the relative cost, they are insensitive to price differences because they do not

themselves have the obligation to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

13. In situations in which two manufacturers sell chemically equivalent drugs and each manufacturer uses a significant detailer force, those products are sold at very similar, high prices, thus eliminating any consumer benefit from that competition. This is in stark contrast to the situation in which the competing seller of a chemically equivalent drug is a generic company without a detailer force. In that case, as explained below, the generic price is significantly lower than the brand price, and consumers benefit as Congress and state legislatures intended.

14. By using detailers to market their products to physicians, brand manufacturers exploit the market "disconnect" and thereby gain or maintain market power, *i.e.*, the power to price their products substantially above marginal cost.

15. The relative unimportance of price in pharmaceutical markets reduces what economists call the price elasticity of demand – the extent to which sales go down when price goes up – which in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing sales. The ability to raise price above marginal cost without losing sales is referred to by economists and antitrust courts as market power or monopoly power. Thus, the net result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain monopoly power.

16. Congress sought to ameliorate the "disconnect," and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by authorizing the manufacture and sale of generic pharmaceuticals. State legislatures continued the same policy by mandating or permitting generic substitution by pharmacists without physician approval. When a

pharmacist receives a prescription for a branded pharmaceutical product, and a generic version of that product is available, state law permits (or in some cases requires) the pharmacist to dispense the generic product in lieu of the branded product. In this way, the importance of price is reintroduced to the product selection decision at the pharmacy counter, and the pharmaceutical marketplace "disconnect" is ameliorated. Branded pharmaceutical manufacturers are no longer able to exploit the market imperfection, their monopoly power dissipates and some of the normal competitive pressures are restored.

17. If Defendants' unlawful conduct had not prevented generic manufacturers from successfully entering the market with a generic version of Abbott's TriCor in April 2002, direct purchasers of TriCor from that time to the present would have saved more than $1 billion in the purchase of fenofibrate.

18. In order to continue to exploit the market "disconnect" – and maintain their monopoly power and thereby avoid losing $1 billion in profits – it was necessary for Defendants to defeat the successful entry of generic TriCor. Beginning in the second half of the 1990's, Defendants foresaw the commencement of generic competition and began devising ways to delay or impede that competition. In response to this anticipated competitive threat, Defendants devised a so-called "life cycle management" scheme which involved (among other things) expensive and unnecessary product modifications that would deliver no benefits to patients but would effectively shield TriCor from generic competition. The scheme was extraordinarily successful – so successful that it was nominated for Abbott's Life Cycle Management Award, given to the pharmaceutical product team that is most effective in impeding generic competition. In the following paragraphs, Plaintiffs explain how Defendants have done exactly that.

**Federal Regulation of New Pharmaceutical Products**

19. Under the federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, approval by the Food and Drug Administration ("FDA") is required before a new drug may be sold in interstate commerce. Premarket approval for a new drug must be sought by filing a new drug application with the FDA, under either section 355(b) or section 355(j) of the Act, demonstrating that the drug is safe and effective for its intended use.

20. In 1984, Congress amended the Food, Drug and Cosmetic Act by enacting the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Amendments or the Hatch-Waxman Act. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications ("NDAs") in order to obtain FDA approval. Instead, such companies are permitted to file Abbreviated New Drug Applications ("ANDAs") and to rely on the safety and effectiveness data already supplied to the FDA by the brand-name manufacturer. The Hatch-Waxman Act also added a number of patent-related provisions to the statutory scheme, as described below. Congress's principal purpose in enacting the Hatch-Waxman Act was "to bring generic drugs onto the market as rapidly as possible." *Mova Pharmaceuticals Corp. v. Shalala*, 140 F.3d 1060, 1068 (D.C. Cir. 1998).

21. New drugs that are approved for sale by the FDA are sometimes protected by a patent or patents, which provide the patent owner with the exclusive right to sell that drug in the United States for the duration of the patent or patents involved, plus any extensions. Under 21 U.S.C. §355(b)(1), a patent holder seeking FDA approval for a new drug is required to file with the FDA "the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and

with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." Patent information received by the FDA with respect to approved drugs is published in a book entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," where it can be found and consulted by future FDA applicants.

22. Generic drugs are drugs which the FDA has found to be bioequivalent to brand name drugs. The first generic competitor to enter a market typically does so at a price at least 30% lower than the price of the equivalent brand-name drug and quickly takes a substantial amount of market share away from the brand-name manufacturer. As additional generic competitors come to market, the price of the generics continues to fall, and their combined market share continues to grow. In some cases, generic competitors sell products equivalent to brand-name prescription drugs for as little as 10% of the price of the brand-name drug, and have captured as much as 90% of the brand-name drug's pre-generic sales.

23. The price competition engendered by generic drug manufacturers benefits all purchasers of the drug, at all levels of the distribution chain, who are able to buy the same chemical substance at much lower prices. Retail pharmacies, such as those owned and operated by Plaintiffs, substitute generic drugs for brand-name drugs wherever possible in order to lower their own costs and those of their customers.

**Abbreviated New Drug Applications for Generic Drugs**

24. Under Hatch-Waxman, a drug manufacturer may seek expedited FDA approval to market a generic version of a brand-name drug by filing an ANDA pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand-name drug.

25. An applicant filing an ANDA for a generic version of a brand-name drug must certify to the FDA that one of the following conditions is satisfied: (1) the brand-name manufacturer has not filed patent information with the FDA (a "Paragraph I certification"); (2) the patent or patents have expired (a "Paragraph II certification"); (3) the patent will expire on a particular future date, and the generic manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or (4) the patent is invalid and/or will not be infringed by the generic manufacturer's product (a "Paragraph IV certification"). 21 U.S.C. §355(j)(2)(A)(vii). If an unexpired patent has been listed in the Orange Book by the brand-name manufacturer, a generic applicant is required to file either a Paragraph III or a Paragraph IV certification.

26. If a generic manufacturer submits a Paragraph IV certification stating that a listed patent is invalid or will not be infringed, it must notify the patent owner of the filing and explain why the patent is invalid or will not be infringed. 21 U.S.C. §355(j)(2)(A)(vii)(IV).

27. The patent owner, upon receiving a Paragraph IV certification from an ANDA applicant, has 45 days in which to initiate a premarketing patent infringement action against the applicant (a cause of action created by Hatch-Waxman). If no action is initiated within 45 days, FDA approval of the generic proceeds without regard to patent issues. If a patent infringement lawsuit is brought within the 45-day window, however, the FDA is automatically barred from granting final approval to the generic applicant until 30 months after the patent holder's receipt of the Paragraph IV certification, unless the patent expires or is held invalid or noninfringed first. 21 U.S.C. §355(j)(5)(B)(iii). This automatic stay of FDA approval is triggered without regard to the merits of the patent holder's lawsuit.

28. The Hatch-Waxman Amendments and the federal regulations that implement them do not give the FDA authority to resolve issues of patent law. The FDA is required to accept as true information it obtains from patent holders, and to withhold its approval of new generic drugs whenever the patent holder presents a litigated dispute (whether genuine or not) regarding the validity or infringement of a patent.

29. The mere filing of an infringement action in response to a Paragraph IV certification, regardless of the underlying merit of the action, gives the brand-name company the functional equivalent of a preliminary injunction blocking the entry of a generic competitor, without the brand company ever having to establish likelihood of success on the merits, irreparable harm, balance of hardships or the public good. Thus, simply by filing the lawsuit, the brand-name company automatically protects its monopoly for up to two and a half years while the infringement action is pending.

30. One result of the statutory and regulatory provisions described above is that brand-name manufacturers have a strong incentive to obtain, list and enforce patents against prospective generic applicants even if the patent is ultimately held to be invalid or not infringed by the generic applicant's proposed generic drug. If a brand-name manufacturer is able to obtain a patent from the Patent and Trademark Office, list the patent in the Orange Book and bring actions under the Hatch-Waxman Act to enforce the patent, the brand-name manufacturer can effectively block the entry of generic competition for up to 30 months. This delay, which is triggered without regard to the merit of the patent holder's claim, can be worth hundreds of millions of dollars to the manufacturer of a successful brand-name drug.

31. FDA regulations provide a second means for an unscrupulous brand manufacturer to delay the onset of generic competition. In order to be substitutable for a branded

product at the pharmacy counter, a generic product must be in the same dosage form and strength as the branded product. FDA regulations, which are concerned only with safety and efficacy and not with effects on competition, permit branded manufacturers to seek FDA approval to modify the dosage form and strength of their existing products. 21 C.F.R. §314.54 (2005). Importantly, the regulations do not require the brand manufacturer to make public the fact that the manufacturer is seeking FDA approval for these modifications. As a result, an unscrupulous brand manufacturer that anticipates the onset of generic competition could modify the dosage form and/or strength of its product from, say, A to $A^1$. Unaware that the branded manufacturer has sought approval to modify its product, the generic manufacturer continues to seek approval to produce a generic version only of A. Before the generic product receives FDA approval and enters the market, the brand manufacturer gets approval for $A^1$ and uses its detailers (and other methods, described below) to encourage physicians to write prescriptions only for $A^1$ instead of A. When the generic manufacturer later gets approval and enters the market with a generic version of A, the generic manufacturer makes few or no sales because its product is not substitutable for $A^1$.

32. A particularly unscrupulous brand manufacturer could combine *both* tactics described above. Such a manufacturer could commence patent litigation against the generic manufacturer in order to obtain the automatic 30-month stay and *then also* use those 30 months to modify its product from A to $A^1$ so that, when the generic manufacturer has endured the 30 months and finally is permitted to enter the market, it is still unable to make substantial sales because the brand manufacturer has in the meantime switched the market from A to $A^1$.

33. A persistent generic manufacturer could file a new ANDA seeking approval to make a generic version of A[1], but under FDA regulations such a filing could trigger a new patent infringement lawsuit and result in another 30-month stay.

**TriCor (Fenofibrate)**

34. TriCor is used to reduce high-levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. TriCor also increases levels of high-density lipoprotein cholesterol ("HDL-C"), sometimes referred to as "good cholesterol," and reduces LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). TriCor is also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides). The active pharmaceutical ingredient in TriCor is fenofibrate.

35. Fenofibrate is a fibrate. Fibrates, statins, bile acid sequestrants, and niacin are categories of cholesterol-lowering drugs. Each of those categories addresses cholesterol conditions differently, each has different side effects (some more serious than others), and each has different efficacy profiles in (i) reducing LDL-C, (ii) raising HDL-C, and (iii) lowering triglycerides. A cholesterol-lowering drug from any of the four categories is not reasonably interchangeable with a drug from another of the categories, and in most cases two drugs within any of the four categories are not reasonably interchangeable with one another.

36. The use of the drug substance fenofibrate as a cholesterol-lowering agent is not new. It has been known since at least the early 1980's, and Fournier's fenofibrate-based drug product Lipidil was approved for use in the United States by at least 1993.

37. On January 23, 1990, the U.S. Patent and Trademark Office (the "PTO") granted Defendant Fournier's application for U.S. Patent 4,895,726 (the "'726 patent"). In its '726 Patent, Fournier claims a dosage form of fenofibrate containing a co-micronized mixture of particles of fenofibrate and a solid surfactant. A solid surfactant is a surface-active agent that interacts with the surfaces of poorly soluble substances, such as fenofibrate, to help them dissolve. A micronized substance is one that has been reduced in size to the micron size range.

38. The specification, claim language and prosecution history of the '726 patent explain what is meant by a co-micronized mixture of fenofibrate and a solid surfactant, and each of these sources makes it clear that such a mixture is obtained when (and only when) fenofibrate and solid surfactant are first mixed together and then micronized as an "intimate" mixture that excludes other components. The patent term "co-micronization of fenofibrate and a solid surfactant" is defined as "the micronization of an intimate mixture of fenofibrate and a solid surfactant." The patent specifically asserts that this co-micronization process improves the bioavailability of the fenofibrate to a greater extent than would be achieved merely by adding a surfactant, by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant. Fournier limited the patent claims to a co-micronized mixture of fenofibrate and a solid surfactant in order to overcome a rejection of the claims as obvious based on the prior art.

39. In December 1999, Fournier filed for reexamination of the '726 patent. The reexamination proceedings for the '726 patent also dictate a construction of the patent claims as requiring that the co-micronization step be performed on a mixture consisting solely of fenofibrate and a solid surfactant and not including additional excipients.

40. In 1997, Fournier granted Abbott an exclusive license to the '726 patent in the United States. Defendants submitted separate NDAs for three strengths of branded fenofibrate capsules that they intended to market. The FDA approved the TriCor 67 mg capsule NDA on February 9, 1998, and the TriCor 134 mg and 200 mg capsule NDAs on June 30, 1999. Defendants brought each of these products to market shortly after receiving FDA approval, and sales of the capsule rose quickly to top $158 million by 2000, and $277 million in 2001.

**Defendants' Exclusionary Scheme to Thwart Generic Competition**

***A. The Illinois Patent Litigation***

41. On December 14, 1999, Novopharm Limited (which was subsequently acquired by Teva Pharmaceuticals USA, Inc. ("Teva")) filed an ANDA with the FDA requesting approval to market generic fenofibrate 67 mg capsules (the "Teva Capsule ANDA") before the expiration of the '726 patent. The Teva Capsule ANDA was later amended by Novopharm to request approval to market generic fenofibrate 134 mg and 200 mg capsules. In connection with the Teva Capsule ANDA, Novopharm certified under Paragraph IV that the proposed generic fenofibrate capsule did not infringe the '726 patent.

42. On May 9, 2000, Impax Laboratories, Inc. ("Impax") also filed an ANDA for fenofibrate capsules. Impax similarly sought approval to market its fenofibrate capsules prior to the expiration of the '726 patent, and accordingly certified under Paragraph IV that its product did not infringe the '726 patent, and duly and timely notified Abbott of its ANDA.

43. On or about April 7, 2000, August 18, 2000 and March 19, 2001, respectively, Defendants initiated a series of infringement actions in the United States District Court for the Northern District of Illinois, against Teva (and its subsidiary, Novopharm) and Impax, alleging that the generic drug manufacturers had infringed the '726 patent under 35

U.S.C. §271(e)(2) (collectively, the "Illinois Patent Litigation"). Under the Hatch-Waxman Act, these suits imposed 30-month stays on FDA approval of Teva's and Impax's generic products. As explained in more detail below, each of these actions was both objectively and subjectively a sham.

44. The FDA granted Impax tentative approval for its fenofibrate capsules on February 20, 2002. The automatic 30-month stay, however, prevented the FDA from granting final approval to Impax's product at that time.

45. On March 19, 2002, the district court granted Teva's motion for summary judgment of non-infringement of the '726 patent in the Illinois Patent Litigation. In so doing, the court construed various elements of the '726 patent, and concluded that Teva's generic fenofibrate capsule product did not literally infringe the terms of that patent. The court also held that Abbott and Fournier were estopped from asserting a range of equivalents which might be construed to include Teva's generic fenofibrate product. The district court's decision was affirmed by the Federal Circuit on March 20, 2003.

46. Teva subsequently received final FDA approval to market its 134 mg and 200 mg capsules on April 9, 2002, and began selling the 134 mg and 200 mg products shortly thereafter. Teva received tentative approval to sell its 67 mg capsule on April 9, 2002, and final approval on September 3, 2002.

47. On March 26, 2003, the Illinois district court granted Impax's motion for summary judgment of non-infringement of the '726 patent based, *inter alia*, on Impax's assertion of collateral estoppel on the basis of the earlier summary judgment that had been granted in the Teva infringement actions. The FDA subsequently granted Impax final approval to market its fenofibrate capsule products on October 28, 2003.

### *B. The First Exclusionary Product Modification*

48. Defendants knew that by merely filing the Illinois Patent Litigation within 45 days of receiving notice of the ANDA filings from Teva and Impax, Defendants would prevent the FDA from granting final approval to Teva and Impax for up to 30 months, despite the fact that Defendants' patent suits lacked merit. Thus, even though Defendants had no basis to file the Illinois Patent Litigation, and knew it, they also knew that doing so would delay competition from Teva's and Impax's generic fenofibrate capsule products for up to 30 months.

49. Using the time that they obtained by filing meritless patent litigation, Defendants modified the dosage form and strength of their TriCor product so that the Teva and Impax generic products would not be substitutable. Defendants then engaged in an additional series of exclusionary actions aimed at thwarting generic competition.

50. As of September 3, 2001, Defendants sold TriCor in the form of a capsule and in strengths of 67 mg, 134 mg and 200 mg (these products are hereafter referred to as "TriCor A"). On September 4, 2001, Defendants obtained FDA approval to market TriCor in the form of a tablet and in strengths of 54 mg and 160 mg (hereafter referred to as "TriCor B"). Defendants obtained this approval while the Illinois Patent Litigation was still ongoing and while the 30-month stays of Teva's and Impax's generic fenofibrate capsules were still in effect. TriCor B offered no benefits of any kind to consumers because it contained the same drug as TriCor A and was bioequivalent to the capsules. However, in this case TriCor B offered huge benefits to Defendants because, unlike TriCor A, there were no pending ANDAs seeking approval to market generic versions of TriCor B at this time.

51. As of September 2001, Abbott knew that the automatic stay would not be lifted by a finding of invalidity or noninfringement stay in the Illinois Patent Litigation until

Spring 2002 at the earliest (briefing on Teva's motion for summary judgment was not complete until January 2002). In or about September 2001, Defendants announced that they would stop all sales of TriCor A, and directed their sales force to market only TriCor B and to urge doctors not to write prescriptions for TriCor A. Through this tactic, Defendants intended to convert the market from TriCor A to TriCor B – that is, to ensure that there were no prescriptions written for TriCor A and no TriCor A in the market with which to fill any such prescriptions – well before generic versions of TriCor A could be launched.

52. Defendants also made a market-wide announcement that beginning October 2001 Defendants would no longer sell TriCor A at all. Defendants knew that a typical retail pharmacy maintains on hand only a 30-60 day supply of most pharmaceutical products. By refusing to sell TriCor A after October 2001, Defendants ensured that by January 2002 – months before the expected entry of generic versions of TriCor A – retail pharmacies would no longer have any branded TriCor A in their inventories.

53. Defendants' draining of TriCor A from the distribution channel prior to generic entry had an anticompetitive purpose and effect. As a result of Defendants' draining, there was little or no TriCor A available in the marketplace from January 2002 until mid-April 2002 (when Teva entered). As explained above, Defendants took steps to ensure that physicians stopped writing prescriptions for TriCor A and started writing prescriptions for TriCor B instead. To the extent that a physician nevertheless wrote a prescription for TriCor A, Defendants' draining of the distribution channel ensured that there would be no TriCor A available at the pharmacy to fill such a prescription. As a matter of good pharmacy practice and continuity of patient care, a pharmacist receiving a prescription for TriCor A during this time would call the

prescribing physician to ask for permission to switch the prescription to the next closest available product, namely TriCor B.

54. Defendants' channel-draining strategy was especially effective at defeating generic substitution because TriCor is a "maintenance medication," i.e., a medication taken for a long period of time for a chronic condition. Prescriptions for TriCor are typically written for a 30-day supply with a number of refills (as many as 12) permitted. Had Defendants not drained the channel of TriCor A, in the period from January 2002 to April 2002 pharmacists could have continued to fill existing, refillable TriCor A prescriptions with branded TriCor A. Then, when Teva's generic product became available in April 2002, pharmacists could have satisfied the remaining refills with generic TriCor A. Defendants' channel-draining tactic ensured that pharmacists would run out of TriCor A before generic TriCor A became available, thereby ensuring that the patient's prescription would have to be switched to TriCor B and preventing Teva from gaining a foothold for the generic in the market.

55. Teva eventually overcame the automatic stay resulting from Defendants' sham patent litigation and entered the market in April 2002. As discussed above, by that time Defendants' exclusionary tactics had ensured that few, if any, new prescriptions were being written for TriCor A and that, through the channel-draining strategy, even refillable TriCor A prescriptions had already been switched to TriCor B.

56. There still existed the possibility, however, that pharmacists receiving a new TriCor B prescription would call the physician to ask permission to dispense generic TriCor A. It is the policy of most retail pharmacies – including Plaintiffs CVS and Rite Aid – to dispense generic pharmaceuticals whenever possible. Defendants were aware of these policies,

however, and took additional exclusionary action to thwart even this possibility of generic competition:

a. More than 75% of all prescriptions are dispensed to patients whose medicines are paid for by a third-party plan (an insurer, HMO, Medicaid, etc). For large retail drugstore chains, the percentage of third-party prescriptions is even higher – in excess of 90%.

b. Most third-party plans subscribe to a data service provided by First Data Bank, which indicates whether a particular drug is a branded drug or a generic drug. Third-party plans use that information to set co-payment levels for their consumers – higher co-payments for branded drugs and lower co-payments for generic drugs.

c. In or about December 2001, Defendants caused First Data Bank to list as "obsolete" the TriCor A product code in its National Drug Data File ("NDDF").

d. Under the policy followed by First Data Bank – a policy that Defendants knew that First Data Bank followed – such a listing of TriCor A resulted in First Data Bank identifying Teva's fenofibrate product as a *branded* pharmaceutical product rather than a generic product. Defendants thereby caused third-party plans to require their customers to pay the higher co-payments (required for receipt of branded pharmaceuticals) in order to receive Teva's fenofibrate product.

e. The practice of many retail pharmacies – including Plaintiffs CVS and Rite Aid – is that they will not call a physician to ask for permission to switch a prescription, even if the pharmacy would benefit financially, unless the patient would also save money. Moreover, very few, if any, patients would agree to a switch from TriCor B to TriCor A unless they would save money. Defendants' causing the listing of TriCor A as obsolete in the NDDF, and thus causing Teva's product to be listed as a branded drug with a high co-payment,

effectively precluded any pharmacy-initiated switching of prescriptions from TriCor B to generic TriCor A.

57. Defendants' causing the listing of TriCor A as obsolete in the NDDF had an anticompetitive effect even before the Teva product was launched. Under the policy of some third-party plans, such a listing of TriCor A caused the plans to no longer cover TriCor A under the plan (*i.e.*, no longer be reimbursed by the plan). In those instances, many pharmacists presented with a prescription for TriCor A (even assuming they still had some branded TriCor A in stock) would call the physician to ask for permission to switch the prescription to a product that is covered by the third-party plan, namely, TriCor B. Defendants' exclusionary conduct in causing the listing of TriCor A as obsolete in the NDDF thus had the effect of causing TriCor A prescriptions to be switched to prescriptions for TriCor B before Teva's generic TriCor A was even launched.

58. TriCor B offered no new benefits to consumers because it contained the same active ingredient as TriCor A and was therapeutically equivalent and bioequivalent to TriCor A. Indeed, Defendants obtained FDA approval for TriCor B by relying on the same clinical studies on which they had relied in seeking approval for TriCor A and by demonstrating to the FDA that TriCor B was bioequivalent to TriCor A. In fact, the introduction of TriCor B was actually disadvantageous to patients taking TriCor A because of the well-documented likelihood of patient confusion inherent in changing patients from one medication to another having a different dosage strength. Thus, Defendants' introduction of TriCor B was expensive, unnecessary and potentially confusing to patients. Defendants launched TriCor B solely in order to thwart and delay generic competition.

59. Defendants obtained FDA approval for a new indication for TriCor B – an indication for "raising HDL-C levels in adult patients with Frederickson Types IIa and IIb dyslipidemia" – by relying on the same clinical studies that had been submitted in support of Defendants' NDA for TriCor A. *See* Medical Officer's Review of New Drug Application, August 30, 2000 (available at http://www.fda.gov/cder/foi/nda/2001/21-203_Tricor_medr.pdf).

60. Although these studies were available to gain this additional approved indication for TriCor A, Defendants failed and refused to seek approval for TriCor A and instead sought it only for TriCor B. Defendants did so for the purpose of inhibiting generic competition. Defendants exploited this illusory differentiation between TriCor B and TriCor A in their marketing efforts.

61. In addition to the medical facts, the economic facts also establish that TriCor B was not a superior product to TriCor A. If TriCor B were in fact superior to TriCor A, Defendants would have developed and marketed TriCor B sooner than they did. Defendants' delay in developing and marketing TriCor B until just before the onset of generic competition evidences the fact that Defendants developed and marketed TriCor B not because it was superior to TriCor A, but because it was part of an effective strategy to thwart generic competition.

62. Likewise, if TriCor B were a superior product to TriCor A, Defendants would have reflected that alleged superiority in the pricing of TriCor B. Rather than pricing TriCor B at a premium to TriCor A, Defendants introduced TriCor B at a price equal to that of TriCor A.

63. Defendants invested significant resources in developing, gaining FDA approval for, and marketing TriCor B. Defendants incurred these substantial expenses in order to sell TriCor B, even though it was therapeutically equivalent and bioequivalent to TriCor A,

was priced the same as TriCor A, and TriCor A was already on the market. Defendants' conduct would make no economic sense but for its effect of thwarting generic competition.

64. The purpose and effect of Defendants' strategy was to thwart generic competition that otherwise would have existed in sales of fenofibrate capsules. By engaging in this scheme, Defendants did not simply choose not to sell TriCor A; they took additional steps that had the purpose and effect of destroying any market for TriCor A (and its generic equivalent) before Teva or Impax could enter the market.

65. As a result of Defendants' exclusionary conduct, Teva and Impax were denied the opportunity to effectively launch their generic fenofibrate products, and were excluded from the most efficient means of distributing their products. When Teva was finally able to launch its fenofibrate capsule, Teva captured only 5% of the fenofibrate market. This is in stark contrast to the "generic erosion" normally observed upon the launch of a generic bioequivalent to a branded product, where generics typically capture from 40% to 80% (or more) of the brand's sales within the first year of launch. As for Impax, Defendants' exclusionary tactics were so effective that Impax abandoned altogether its plans to enter with generic TriCor A. As a direct and proximate result of Defendants' overall scheme to monopolize, Defendants effectively destroyed generic competition that should have started in April 2002, and have improperly maintained a 95% share of the market for fenofibrate products.

### *C. The Delaware Patent Litigation*

66. Having successfully shielded their product (and monopoly profits) from generic competition, Defendants were quick to return to the same strategy when generic competitors once again threatened to enter the fenofibrate market. This time before this Court, Defendants executed their scheme of reflexively filing patent suits against generic competitors,

regardless of the lack of merit in such suits, while using the resulting delay to again modify TriCor in order to thwart generic substitution.

67. Recognizing that Defendants had successfully defeated the launch of generic TriCor A, Teva started over and initiated the process of seeking FDA approval to market generic TriCor B. On or around June 17, 2002, Teva filed with the FDA an ANDA for its generic fenofibrate 54 mg and 160 mg tablets (the "Teva Tablet ANDA"), along with a Paragraph IV certification that the ANDA did not infringe the '726 patent or two additional patents that Defendants had subsequently listed in the Orange Book as covering the TriCor tablets, U.S. Patent No. 6,074,670 (the "'670 patent"), which issued on June 13, 2000, and U.S. Patent No. 6,277,405 (the "'405 Patent"), which issued on August 21, 2001. On or around August 21, 2002, Teva gave notice to Defendants of the filing of the Teva Tablet ANDA and the Paragraph IV certifications made therein. Abbott received notice of Teva's initial ANDA filing on August 26, 2002.

68. Teva subsequently amended its ANDA, on July 29, 2003 and December 17, 2003, respectively, by filing two additional Paragraph IV certifications, one for U.S. Patent 6,589,552 (the "'552 patent") and one for U.S. Patent 6,652,881 (the "'881 patent"), shortly after Abbott listed each of these patents in the Orange Book as claiming TriCor. Teva duly served Abbott with notice of each of its certifications, which prompted additional infringement complaints filed within 45 days of this notice.

69. In three separate complaints filed in the United States District Court for the District of Delaware (later consolidated into a single action), Abbott alleged that Teva had infringed the five patents as to which Teva had filed Paragraph IV certifications. The first complaint, filed on October 4, 2002, alleged infringement of the '726 Patent, the '670 patent, and

the '405 patent; the second complaint was filed on August 29, 2003, alleging infringement of the '552 patent, and the third complaint was filed January 22, 2004, alleging infringement of the '881 patent.

70. By virtue of the filing of the first and second complaints, Defendants imposed two successive 30-months stays under the Hatch-Waxman Act, thus barring FDA approval of Teva's ANDA. The first 30-month stay expired on February 26, 2005, and the second 30-month stay was scheduled to expire in February 2006. Because (and only because) of the modifications to the Hatch-Waxman Act made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Abbott is not entitled to a third stay based on the third complaint for infringement of the '881 patent.

71. Similarly, Impax also sought to enter the fenofibrate market in the United States by filing an ANDA for fenofibrate tablets in or around December 2002. In connection with this ANDA, Impax submitted Paragraph IV certifications that the ANDA did not infringe the '726, the '670 and the '405 patents. As they had against Teva, Defendants sued Impax, asserting infringement of the '670 and the '405 patents. The filing of the initial infringement case, on January 23, 2003, triggered an automatic 30-month stay of approval of Impax's Tablet ANDA by the FDA. The issuance and Orange Book listing of the '552 patent resulted in an additional infringement case against Impax, and an additional 30 month stay. The listing of the '881 patent resulted in yet another suit against Impax, but again, as in the case of the suits against Teva, there was no additional 30-month stay associated with that infringement suit.

72. On March 5, 2004, the FDA granted tentative approval to Impax's and Teva's tablet ANDAs, which means that the FDA had determined that these generic products are bioequivalent to TriCor tablets of the same dosage strength, and that Teva and Impax have

satisfied all the other regulatory requirements, such as demonstrating safety and efficacy, for the sale of their fenofibrate product in the United States. The tentative approvals by the FDA would have been final approvals but for the successive 30-month stays resulting automatically from Abbott's and Fournier's filing and maintenance of their patent infringement actions against Impax and Teva concerning the tablet ANDAs. Both Teva and Impax represented to this Court that, absent the 30-month stays, they would have received final approval on March 5, 2004, and would have entered the market shortly thereafter with 54 mg and 160 mg generic tablets.

73. If it had not been for the first exclusionary product modification from TriCor A to TriCor B, Teva and Impax likely would not have submitted ANDAs for tablets and, even if they had, Defendants likely would not have filed the patent cases that kept Teva's and Impax's generic tablets off the market after March 5, 2004, because generic erosion would already have occurred. Thus, but for the first product modification, either the product would have been marketed exclusively in capsule form or, even if tablets had been introduced, generic versions of the tablet would have dominated the market by early 2004.

74. The various infringement suits in Delaware against Teva and Impax were consolidated and/or coordinated before this Court (the "Delaware Patent Litigation"). The Delaware Patent Litigation was heavily litigated by and among Defendants, Teva and Impax, and trial was scheduled to begin on December 6, 2004. Defendants succeeded in getting this trial date pushed back six months to June 6, 2005, however, through the filing of the subsequent infringement actions related to the '552 patent. Then, with less than a month to go before trial, Defendants, having already achieved the goal of the suits – delays – voluntarily moved to dismiss all the pending Delaware infringement actions. Defendants' motion for voluntary

dismissal demonstrated that the Defendants' intention all along was not to pursue the merits of their infringement claims, but merely to delay generic competition.

**D. Defendants' Sham Patent Litigation**

75. All of the Illinois Patent Litigation, and a substantial portion of the Delaware Patent Litigation filed by Defendants were both objectively and subjectively a sham.

**Non-infringement**

76. In the Illinois Patent Litigation, Abbott and Fournier alleged that Teva's and Impax's proposed generic versions of TriCor A infringed Fournier's '726 patent. This allegation of patent infringement was objectively baseless, and Defendants knew that it was objectively baseless. The Illinois Patent Litigation was brought not because Defendants believed they had a realistic chance of prevailing in the litigation, but because by filing the litigation, regardless of its outcome, Defendants were able to delay generic competition for up to 30 months.

77. As explained earlier, the claims, specification, original prosecution history and reexamination prosecution history of the '726 patent made it absolutely clear that the patent is limited to a fenofibrate formulation in which co-micronization is performed on a mixture of fenofibrate and a solid surfactant without the presence of additional excipients. As Defendants were aware from Novopharm's paragraph IV certification, Teva's proposed generic capsule was not made using co-micronization.

78. Under Teva's process, fenofibrate was first pre-micronized on its own and in the absence of any other ingredient. The pre-micronized fenofibrate was then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crossprovidone. After some additional steps, including wet granulation and drying, the dried, granulated mixture was

then dry blended with additional excipients to produce granules that can pass through a #16 mesh screen. The granulated mixture was then blended again, weighed and stored for eventual encapsulation into gelatin capsules. Impax's proposed generic capsule was made using a similar process.

79. Since it was obvious that the '726 patent claims were limited to a formulation in which fenofibrate and a solid surfactant are co-micronized in the absence of other excipients, and equally obvious that Teva's and Impax's proposed products were not made using such a process, no reasonable litigant could have realistically expected to prove infringement against either generic applicant under 35 U.S.C. § 271(e)(2)(A). In fact, neither Abbott nor Fournier expected to do so. Abbott and Fournier knew that it was only a matter of time before their claim was defeated, but time was exactly what they were seeking. Abbott and Fournier needed to delay approval of Teva's and Impax's ANDAs long enough for them to convert the market to TriCor B, and the Illinois Patent Litigation gave them sufficient time to do so.

80. As noted above, the Illinois district court granted summary judgment to Teva in the Illinois Patent Litigation in March 2002, finding that the '726 patent claims had to be construed in the manner described in the patent and that, so construed, Teva's proposed generic capsule did not infringe any of those claims. The district court had no difficulty in reaching this conclusion. The trial court's ruling was affirmed only a year later by the United States Court of Appeals for the Federal Circuit, which likewise had no difficulty in rejecting Defendants' position. As the Federal Circuit pointed out in its opinion, the specification of the patent and other circumstances made it "abundantly clear that 'co-micronization of . . . fenofibrate and a solid surfactant' should be construed as referring to co-micronization of a mixture consisting

essentially of fenofibrate and solid surfactant." *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003).

81. Even after their defeat in the action against Teva, Defendants continued to press the same infringement allegations against Impax. When Impax argued that Defendants were collaterally estopped by the claim construction ruling issued by the district court in the prior litigation against Teva, Defendants made the frivolous arguments that collateral estoppel did not apply because (1) "a district court is not bound by another court's claim construction;" (2) the district judge in the prior action "misunderstood the pharmaceutical technology and issues in the '726 patent;" and (3) the ruling was on appeal. *See Abbott Laboratories v. Impax Laboratories, Inc.*, 2003 WL 1563426, *4-5 & n.4 (N.D. Ill. 2003). Each of these arguments was contrary to controlling Supreme Court or Federal Circuit precedent, and each was easily rejected by the Illinois district court.

82. Defendants alleged in the Delaware litigation that Teva's proposed generic version of TriCor B infringed the '726, '670, '405, '552 and '881 patents. Defendants had no factual basis for such allegations at the time that they were made. Defendants had performed no tests of any kind on the Teva product before alleging infringement, despite the fact that Teva had provided samples of its product to Defendants. Defendants made no effort to determine whether or not there was infringement before filing suit. Defendants did not conduct any tests on any unexpired Teva fenofibrate tablets until May of 2005, almost three years after they had filed the first of the Delaware patent cases.

83. In connection with each of the paragraph IV certifications made by Teva, Teva was required to and did provide Defendants with a detailed statement explaining why Teva's proposed generic products did not infringe any of Defendants' patents. Teva also

provided Defendants with technical material from its ANDA demonstrating the lack of infringement.

84. In fact, Defendants did not file the Delaware Patent Litigation because they believed that they had a chance of prevailing in the litigation or because they genuinely desired to prevail. Defendants filed the Delaware Patent Litigation solely because, merely by filing those cases, they were able to trigger a regulatory delay of up to 30 months in FDA approval of Teva's ANDA.

**Inequitable Conduct**

85. Defendants were guilty of inequitable conduct in obtaining the '881 patent, and Defendants knew that they were guilty of inequitable conduct. Inequitable conduct renders a patent unenforceable. In listing and attempting to enforce a patent that they knew to be unenforceable, Defendants engaged in conduct that was both objectively and subjectively a sham.

86. The '881 patent resulted from Application No. 10/288,425, filed November 6, 2002. The '881 patent is owned by Fournier. According to the '881 patent, the poor solubility of fenofibrate interferes with its bioavailability, causing bioavailability to be "incomplete." The '881 patent asserts that there is a need to improve fenofibrate bioavailability by achieving a dissolution that is "close to 100% over very short periods of time."

87. The '726 patent, also owned by Fournier, describes a fenofibrate formulation that is prior art to the '881 patent. The '726 patent also discloses a method of improving fenofibrate solubility, and thus bioavailability, by co-micronizing fenofibrate with a surfactant. Lipanthyl 200M, a fenofibrate pharmaceutical product sold by Fournier in Europe, is an embodiment of the '726 patent and is the same formulation as TriCor A.

88. The '881 patent defines the requirements for dissolution as greater than 10% in five minutes, 20% in ten minutes, 50% in 20 minutes and 75% in 30 minutes in a medium comprised of 1200 ml water to which 2% Polysorbate 80 is added, or of 1000 ml of water to which 0.025 M sodium lauryl sulfate is added, with a blade rotation speed of 75 rpm. The patent asserts that these higher dissolution requirements are met "by a new method for preparing a pharmaceutical composite by spraying a suspension of the active ingredient onto an inert hydrosoluble carrier."

89. During the prosecution of the application that led to the '881 patent, the Examiner rejected prosecution claims 1-14 and 22-41 as obvious over the '726 patent. In response to this rejection, Fournier distinguished the '726 patent by its dissolution profile, arguing that the invention being claimed "has an unexpectedly superior dissolution profile" compared to the prior art disclosed in the '726 patent.

90. The Examiner allowed the claims, finding that the '726 patent failed to teach a composition having a dissolution of at least 10% in five minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes. According to the Examiner's Statement of Reasons for Allowance, the "instant invention [claimed in the '881 patent] has an unexpectedly superior dissolution profile compared to Lipanthyl® 200M (as taught by [the '726 patent])." Thus, the dissolution profile of Lipanthyl 200M was material to the allowance of the claims in the '881 patent.

91. Philippe Reginault is a named inventor of the '726 patent. He served as Fournier's director of pharmaceutical development in charge of formulation, scale up and analytical development from 1988 to 2002. Beginning in 2002, Reginault served as Fournier's director of pharmaceutical technologies evaluation.

92. Reginault conducted tests and submitted declarations to the PTO during the prosecution of the application that led to the '881 patent. These declarations falsely represented to the PTO that the dissolution rates of prior-art fenofibrate compositions were lower than they actually were, and failed to disclose results showing dissolution rates for such compositions that were higher than those provided to the PTO. Reginault did not provide test results relating to Lipanthyl 200M, the formulation cited in the Examiner's Statement of Reasons for Allowance, although Reginault had such results in his possession and such results were material.

93.

REDACTED

94.

REDACTED

95. Reginault did not disclose dissolution data for Lipanthyl 200M that were much better than those submitted to the PTO in the patent application that led to the '881 patent.

96. Reginault did not disclose dissolution data obtained by Fournier for TriCor micronized capsules in 0.025M sodium lauryl sulfate that was much better than that submitted to the PTO.

97. In addition to better dissolution test results, Reginault failed to disclose that the dissolution results for the capsule embodiments of the prior art provided to the PTO may have been lower than the actual dissolution of the active ingredient because of hardening of the capsule gelatin during storage.

98. The information not disclosed by Reginault was highly material to the patentability of the claimed invention.

99. Reginault was aware of the duty to disclose material information when providing submissions to the PTO during the prosecution of a patent application and acknowledged that duty.

100. The information withheld by Reginault was withheld with an intent to deceive the Patent Examiner.

101. In listing and enforcing the '881 patent, Defendants sought to enforce a patent that they knew to be unenforceable. Since the facts evidencing their inequitable conduct were certain to come out during the litigation, Defendants' effort to enforce the patent was doomed to fail. In fact, no reasonable litigant could have realistically expected to prevail in the case.

102. Defendants brought the '881 patent litigation pursuant to a policy of filing patent infringement actions without regard to their merit and solely for the purpose of delaying generic entry.

***D. The Second Exclusionary Product Modification***

103. Defendants' abandonment of the Delaware Patent Litigation reveals their true motive for commencing those actions in the first place – to provide Defendants once again with the time needed to modify their TriCor product for the purpose of defeating generic substitutability. During the pendency of the Delaware Patent Litigation, Defendants were planning another product modification, which they implemented in late 2004, while the stay resulting from their Delaware Patent Litigation was still in place.

104. On November 5, 2004, Defendants obtained approval for a new NDA for another formulation of TriCor, this time in tablets of 48 and 145 mg strengths (hereafter referred to as "TriCor C"). TriCor C contains the same active ingredient as TriCor A and TriCor B. By virtue of the modified strengths, however, a prescription written for TriCor C cannot be filled with generic TriCor A or generic TriCor B.

105. In addition to modifying the strengths, Defendants also included in TriCor C patented nanotechnology that allows patients to take TriCor other than with meals. Defendants did not develop this technology themselves, but licensed it from Elan Corporation, plc. Defendants entered an exclusive license with Elan for use of the patented technology with fenofibrate worldwide, and have prohibited Elan from researching and/or developing any oral formulation of fenofibrate using its nanotechnology. Defendants included the licensed technology in TriCor C for the purpose of defeating generic substitutability.

106. Having obtained FDA approval for TriCor C while the 30-month stays were still in place, Defendants repeated all of the exclusionary conduct in which they had engaged in connection with the modification from TriCor A to TriCor B:

a. Abbott and Fournier then began marketing TriCor C and stopped selling TriCor B, just as they had done in connection with the switch from TriCor A to TriCor B. Defendants directed Abbott's detailers to market only TriCor C to the exclusion of TriCor B, and to urge physicians not to write prescriptions for TriCor B;

b. Defendants stopped selling TriCor B altogether and drained the distribution channel of TriCor B so that pharmacists presented with a TriCor B prescription would call the physician to request a switch to TriCor C;

c. Defendants caused First Data Bank to list the TriCor B product as obsolete in the NDDF, with the purpose and effect of causing third-party plans to no longer cover branded TriCor B and of causing plans to charge their customers the higher, branded co-payment for Teva's or Impax's TriCor B product.

107. Defendants developed at least one new twist for the TriCor C exclusionary scheme. Apparently unsatisfied with their prior efforts to drain the distribution channel of TriCor A, Defendants intensified those efforts in connection with draining the channel of TriCor B. This intensified tactic involved a modification of Abbott's policy regarding returned goods. Under Abbott's standard returned-goods policy, wholesalers and retailers do not receive a refund based on the amount of unsold product actually returned to Abbott. Instead, Abbott simply provides a 1% returned-goods allowance at the time of purchase. As part of their scheme to drain all TriCor B from the distribution channel, however, Defendants changed the returned-goods policy with respect to TriCor B. In or about March 2005, Defendants announced that wholesalers and retailers could return all unsold TriCor B, regardless of quantity, and receive a refund in the amount of the full purchase price (less certain discounts and the 1% allowance). This gave a significant financial incentive for wholesalers and retailers to return all TriCor B and eliminate it from their inventories. This exclusionary tactic was intended to ensure that the distribution channel would be drained of TriCor B before the generic competitors could enter the market. Defendants' channel-draining strategy would not have made economic sense absent the intended harm to generic competition.

**E. Effects of Defendants' Unlawful Conduct**

108. Defendants' exclusionary conduct has delayed or prevented the sale of generic fenofibrate in the United States, and has unlawfully enabled Defendants to sell TriCor at

artificially inflated prices. But for Defendants' illegal conduct, generic competitors would have been able to successfully market generic versions of TriCor A by April 9, 2002, and additional generic competitors would have entered the market thereafter. TriCor B would never have been introduced. Even if TriCor B had been introduced, generic competitors would have begun marketing generic versions of TriCor B by at least March 5, 2004, and additional generic competitors would have entered the market thereafter. Under no circumstances would Defendants have developed or marketed TriCor C.

109. Defendants' pattern and practice of reflexively filing Hatch-Waxman patent cases and using the resulting 30-month stays to convert the market to a new formulation that is not subject to generic competition, while simultaneously discontinuing the old formulation, is exclusionary and unreasonably restrains competition on the merits. Defendants' conduct has allowed, and continues to allow, them to maintain a monopoly and exclude competition in the relevant market, to the detriment of all fenofibrate purchasers.

110. If manufacturers of generic fenofibrate had been able to enter the marketplace and effectively compete with Defendants, Plaintiffs would have substituted lower-priced generic TriCor for the higher-priced brand-name TriCor for the vast majority of their fenofibrate requirements and/or would have received lower prices on their purchases of branded TriCor.

111. As a result of Defendants' unlawful and exclusionary conduct, Plaintiffs were forced to continue to purchase branded fenofibrate from Defendants at monopoly prices rather than generic fenofibrate from a generic manufacturer at much lower prices. Plaintiffs continue to be overcharged by paying higher prices for fenofibrate than would have prevailed in the absence of Defendants' unlawful conduct.

**Relevant Product and Geographic Markets**

112. The relevant product market is the sale of fenofibrate – *i.e.*, TriCor (in its various formulations) and its generic equivalents. The relevant geographic market is the United States. A firm that was the only seller of prescription drugs containing fenofibrate in the United States could and would impose a significant, non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by Defendants' ability to charge supracompetitive prices for fenofibrate during the period in which Defendants have lacked generic competition.

113. During the relevant period, Defendants' share of the relevant market has been 100% or nearly 100%.

114. Defendants' unlawful actions were taken for the purpose of maintaining Defendants' market power in the relevant market and allowing them to continue to charge monopoly prices free of generic competition.

**Count I - Monopolization (15 U.S.C. § 2)**

115. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 114 above.

116. At all relevant times, Defendants possessed monopoly power in the relevant market.

117. During the relevant period, Defendants willfully and unlawfully maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants' exclusionary conduct included the following:

a. modifying TriCor A to TriCor B, and modifying TriCor B to TriCor C;

b. directing their detailers to market only TriCor B (and, later, TriCor C) and to urge physicians not to write prescriptions for the other versions for which generic substitutes would soon be available;

c withdrawing TriCor A (and, later, TriCor B) from the market and draining the distribution chain of those versions of the product;

d. causing First Data Bank to list TriCor A (and, later, the TriCor B) as obsolete in the NDDF;

e. failing and refusing to obtain for TriCor A the additional indication that they obtained for TriCor B;

f. entering into an exclusive license with Elan Corporation, plc for the nanotechnology used in TriCor C;

g. engaging in sham litigation; and

h. implementing a unified exclusionary scheme that included all of the tactics listed in (a) - (g).

118. Defendants undertook all of this conduct with the purpose and effect of delaying generic competition, and, once generic entry occurred, of inhibiting generic substitutability for TriCor. Defendants' actions, individually and collectively, were intended to and did suppress rather than promote competition on the merits.

119. Plaintiffs have been injured in their business and property by reason of Defendants' unlawful monopolization. Plaintiffs' injury consists of paying higher prices for fenofibrate than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs'

injury is of the type that the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

120. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court.

**Count Two**
**Conspiracy in Restraint of Trade (15 U.S.C. § 1)**

121. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 through 114 above.

122. At all relevant times, Defendants Abbott and Fournier have been engaged in a contract, combination or conspiracy in unreasonable restraint of trade, the purpose and effect of which have been to delay, impede and restrain competition in the relevant market.

123. At all relevant times, Defendants have possessed market power in the relevant market.

124. During the relevant period, Defendants willfully and unlawfully maintained their market power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included each of the following (at various times):

a. modifying TriCor A to TriCor B, and modifying TriCor B to TriCor C;

b. directing their detailers to market only TriCor B (and, later, TriCor C) and to urge physicians not to write prescriptions for the other versions for which generic substitutes would soon be available;

c withdrawing TriCor A (and, later, TriCor B) from the market and draining the distribution chain of those versions of the product;

d. causing First Data Bank to list TriCor A (and, later, the TriCor B) as obsolete in the NDDF;

e. failing and refusing to obtain for TriCor A the additional indication that they obtained for TriCor B;

f. entering into an exclusive license with Elan Corporation, plc for the nanotechnology used in TriCor C;

g. engaging in sham litigation; and

h. implementing a unified exclusionary scheme that included all of the tactics listed in (a) - (g). Defendants undertook all of this conduct with the purpose and effect of delaying and/or inhibiting generic competition. Defendants' actions, individually and collectively, were intended to and did suppress rather than promote competition on the merits.

125. Defendants' collective conduct has had a substantially adverse effect on competition in the relevant market.

126. Plaintiffs have been injured in their business and property by reason of Defendants' unlawful conspiracy in restraint of trade. Plaintiffs' injury consists of paying higher prices for fenofibrate than would have been paid in the absence of Defendants' illegal conduct. Plaintiffs' injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

127. Defendants' violations threaten continuing loss and injury to Plaintiffs unless enjoined by this Court

WHEREFORE, Plaintiffs pray for judgment against Defendants and for the following relief:

A. A judgment for three times the damages actually sustained by Plaintiffs, as determined by a jury;

B. A declaration that Defendants have violated the antitrust laws in the ways described above;

C. Permanent injunctive relief which enjoins Defendants from continuing their illegal conduct, and requires them to take affirmative steps to dissipate the effects of their prior violations;

D. The costs of this suit, including a reasonable attorneys' fee; and

E. Such other and further relief as the Court deems just and proper.

**Jury Demand**

Plaintiffs demand a trial by jury for all claims so triable.

Respectfully Submitted,

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**Certificate of Service**

I hereby certify that a true and correct copy of the foregoing was served this 23rd day of September 2005 upon all counsel on the attached service list.

Joseph T. Lukens

**CERTIFICATE OF SERVICE**

I, Elizabeth M. McGeever, hereby certify that on this 23rd day of September, 2005, my co-counsel, Joseph T. Lukens, Esquire, caused a copy of the foregoing AMENDED COMPLAINT to be served upon all counsel on the attached service list.

Elizabeth M. McGeever (#2057)

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Case No 05-340 (KAJ), District of Delaware

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